

Notice of Allowability

Application No.

09/674,183

Examiner

S. Devi, Ph.D.

Applicant(s)

RAPPUOLI ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/10/04.
2. ☒ The allowed claim(s) ~~is~~ are 5, 6, 13-15 and 33-44.
3. ☒ The drawings filed on 30 August 2004 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input checked="" type="checkbox"/> Other <u>Attachment</u> . |

ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' After-Final Amendments

- 1) Acknowledgment is made of Applicants' after-final amendments filed 08/30/04 and 09/10/04 in response to the final Office Action mailed 04/26/04. The former is non-compliant and therefore has not been entered. The latter has been entered.

Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Ms. Roberta Robins provided the authorization for this Examiner's amendment in a telephone interview on 10 September 2004.

This application has been amended as indicated below:

Before line 3 on page 1 of the specification, the following paragraph has been inserted:

--This application is a national stage application, filed under 35 U.S.C. 371, of the PCT application PCT/IB99/00844, filed 04/27/1999 and claims foreign priority to application, 988932.9 filed 04/27/1998 in Great Britain.--

Status of Claims

- 3) Claims 5, 6, 13-15 and 33-40 have been canceled via the amendment filed 09/10/04.
Claims 4, 8, 10-12, 16 and 21 have been canceled via the amendment filed 08/30/04.
Claims 5, 6, 13-16 and 33-44 are pending and are under examination.

Rejection(s) Moot

- 4) The rejection of claims 4, 8, 10-12 and 16 made in paragraph 10(b) of the Office Action mailed 08/01/03 and maintained in paragraph 25 of the Office Action mailed 04/26/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.
- 5) The rejection of claim 4 made in paragraph 10(d) of the Office Action mailed 08/01/03 and maintained in paragraph 26 of the Office Action mailed 04/26/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 6) The rejection of claims 4, 8 and 21 made in paragraph 10(i) of the Office Action mailed 08/01/03 and maintained in paragraph 27 of the Office Action mailed 04/26/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the

claims.

7) The rejection of claim 4 and those that depended therefrom made in paragraph 28 of the Office Action mailed 04/26/04 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claim.

8) The rejection of claims 4, 8, 10 and 21 made in paragraph 30 of the Office Action mailed 04/26/04 under 35 U.S.C. § 102(b) as being anticipated by Brown *et al.* (EP 0 270 295 A2) as evidenced by Falugi *et al.* (*Eur. J. Immunol.* 31: 3816-3824, 2001 – already of record), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

9) The rejection of claims 5, 6 and 13-15 made in paragraph 10(b) of the Office Action mailed 08/01/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of the Applicants' amendments to the claims and the amendments made via this Examiner's amendment.

10) The rejection of claims 5 and 6 made in paragraph 10(d) of the Office Action mailed 08/01/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments and arguments.

11) The rejection of claims 5 and 6 made in paragraph 10(i) of the Office Action mailed 08/01/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

12) The rejection of claims 33-40 made in paragraph 29(a) of the Office Action mailed 04/26/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

13) The rejection of claims 43 and 44 made in paragraph 29(b) of the Office Action mailed 04/26/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the base claim(s).

Remarks

14) Claims 5, 6, 33-38, 41, 42, 13, 14, 39, 40, 15, 43 and 44, now renumbered as claims 1, 2, 3-8, 9, 10, 11, 12, 13, 14, 15, 16 and 17 respectively, are allowed. The various CD+ T cell epitopes, P23TT, P32TT, P21TT, PFT3, P30TT, P2TT, HBVnc, HA, HbsAg, MT and hsp70, recited in claims 5 and 6 are the specific CD4+ T cell epitopes having the structure or SEQ ID numbers as depicted in Table 1 of the instant specification, and must be interpreted as such. The term now

introduced to claims 5 and 6 'PFT3' to replace the previously recited 'PfCs' is not new matter since the instant specification contains descriptive support for both the synonymous terminologies (see original claims and Table 1). Structurally or amino acid composition-wise, the two protein epitopes are identical as explained by Applicants on page 6 of the after-final arguments filed 09/10/04. The expansion provided for 'HA' and 'MT' in claim 5 is not new matter as is clear from the teachings of the reference of Alexander *et al.*, 1994 cited in Table I of the instant specification and from their structure.

15) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306.

16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER